Application No.: 10/516,600

REMARKS

This amendment is submitted in response to the final Office Action mailed December 9, 2009, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on March 9, 2010. Accordingly, this amendment is timely submitted. Although the Applicant believes that no fees are due at this time, the Commissioner is hereby authorized to charge Deposit Account No. 50-4498 in the name of Nestle Nutrition for any fees that maybe deemed owed or credit any overpayment related to the above-identified application.

The Applicant has fully considered the Office Action and cited references and submits this Reply and Amendment in response to the outstanding rejections. Reconsideration of the application for patent is requested.

Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 22, 24-30, 32, 33, 35-38, and 52-63, as amended, appear in this application for the Examiner's active consideration. Claim 22 is amended to include the recitation of claim 45. Claims 45-47 are cancelled herein. The amendments do not introduce new matter or raise any new issues that would require further consideration or search, but place the application in better form for appeal by reducing or simplifying the issues for appeal. Accordingly, the entry of the amendments is respectfully requested.

Reconsideration in view of the above amendments and the following remarks is respectfully requested.

The Office Action incorrectly indicates that claims 29, 38, and 45-59 are withdrawn as being directed to non-elected inventions or species. Applicant respectfully notes that claims 52-55 are directed to the elected invention, i.e., a composition comprising one or more viscous soluble fiber(s) and one or more viscosity-lowering protein(s), and depend from elected claim 30. Accordingly, these claims should be examined on the merits at this time.

Claims 29 and 38 also depend from claims 22 and 30, so that it is believed that these claims should be rejoined. Also, it is understood that method claims 56-63, directed to methods

of using the claimed compositions, will be rejoined when the pending composition claims from which they depend are allowed.

Claims 22, 26-28, 30, and 35-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Australian Patent Application No. AU 9873118 A to Jaussan et al. ("Jaussan"). Applicant respectfully disagrees with the rejection.

Independent claim 22 recites a composition comprising one or more viscous soluble fiber(s) and one or more viscosity-lowering protein(s), wherein the soluble fiber(s) is selected from agar, alginates, carubin, pectin, beta-glucan, carrageenan, furcellaran, arabinogalactan, pectin and its derivatives, cellulose and its derivatives, scleroglucan, psyllium and gums and the protein(s) is moderately hydrolyzed and is selected from wheat protein, egg protein, collagen, whey protein, casein, soy protein, pea protein, muscle protein, gluten, fibrillar protein, silk protein and combinations thereof. The viscosity-lowering protein(s) is present in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature such that the composition is less viscous than the same composition in which the viscosity-lowering protein is absent. The composition does not comprise inulin. Independent claim 30 recites a non-viscous composition consisting essentially of such viscous soluble fiber(s) and viscosity-lowering protein(s). As explained in the specification, using moderately hydrolyzed viscosity-lowering protein provides significant advantages, such as modulated viscosity. (Published Application, US 2006/0099324, ¶¶ [0017], [0039].)

By contrast, Jaussan relates to a nutritional composition for diabetic patients comprising certain amounts of a protein source, a lipid source, a carbohydrate source, and a fiber mixture. The fiber mixture includes a viscous soluble fiber and inulin, a hydrolysate of inulin or both. The Jaussan composition differs from the claims as requiring inulin or a hydrolysate of inulin. Also, Jaussan does not disclose or suggest using any hydrolyzed viscosity-lowering protein. Thus, Jaussan does not anticipate or render obvious the claimed composition, which comprises particular fibers and proteins and which does not include any inulin or hydrolysate thereof.

Accordingly, the rejection over Jaussan should be withdrawn.

Claims 22, 25-27, 30, 33, 35, and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,470,839 to Laughlin et al. ("Laughlin").

Laughlin relates to a moderate to low carbohydrate, high fat formulation, wherein the fat includes medium chain triglycerides. The fat comprises about 30 to 50% of the total calories of

the formulation. Thus, although the formulation of Laughlin may further include protein and dietary fiber, Laughlin does not disclose or suggest using moderately hydrolyzed protein in the manner recited in the claims. Laughlin's formulation is further different from the composition recited in claim 30, and the claims depending therefrom, as requiring a high fat content. While Laughlin discloses a viscosity of 90 CPS, this does not anticipate or render obvious the claims, because Laughlin's formulation has significantly different components, such as various fat components and there is no suggestion that the Laughlin formulation could include any moderately hydrolyzed protein. Because of these differences, the Laughlin formulation would have very different viscosity characteristics from the claimed composition. Laughlin therefore does not anticipate or render obvious the claimed composition.

Accordingly, the rejection over Laughlin should be withdrawn.

Claims 22-28, 30, 32, 33, and 35-37 are rejected under 35 U.S.C § 102(b) as being anticipated by European Patent Application No. 0323510 A1 to Ohta et al. ("Ohta").

Ohta discloses a food composition that comprises water-soluble edible fibers and proteins having an isoelectric point in an acidic region such that an aqueous solution of the composition gels when in contact with gastric juice. The composition is dissolved in hot water to be taken as an aqueous solution.

The Examiner points to Figure 1 of Ohta as teaching a viscosity below 100 cPs. However, Figure 1, as well as the other figures and examples in Ohta, shows viscosity of the composition at 70°C and 40°C, wherein the viscosity increases with the temperature reduction. Thus, Ohta does not disclose a composition wherein one or more viscosity-lowering protein is moderately hydrolyzed and is present in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPa at room temperature. Further, in Ohta, the viscosity increase was significant when the temperature was lowered from 70°C to 40°C. For example, the viscosity increased nearly twice in Figure 1, nearly seven-fold in Figure 2, and nearly five-fold in Figure 3. (Ohta at 7-9, FIGS. 1-3.) In view of such disclosure, one of ordinary skill in the art would not read Ohta as disclosing the claimed composition.

Thus, the rejection over Ohta should be withdrawn.

Claims 22, 26-28, 30, and 35-37 are rejected under 35 U.S.C § 102(b) as being anticipated by U.K. Patent Application No. 2021948 A to Heath et al. ("Heath").

Heath relates to a water-miscible gum composition used for reducing cholesterol and/or glucose level in the blood. The composition is made by coating fine particles of gum with a layer of substance having a greater tendency to absorb water than the gum. The coating is preferably starch and/or protein. Thus, Heath relates to a complete different composition from the claimed composition, and does not anticipate or render obvious the claims. Further, while Heath's coated composition may contain a fiber and a protein, Heath does not disclose or suggest providing specific moderately hydrolyzed proteins as recited in the claims, in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature.

Accordingly, the rejection over Heath also should be withdrawn.

Claims 22, 24-28, 30, 32, 33, and 35-37 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Jaussan, Laughlin, Ohta, or Heath. Applicant respectfully submits that these claims are neither anticipated by nor obvious over the cited references for the reasons explained above. In particular, Jaussan relates to a composition comprising certain amounts of a protein source, a lipid source, a carbohydrate source, and a fiber mixture that includes inulin, a hydrolysate of inulin or both; Laughlin relates to a formulation having carbohydrate and a high fat content; Ohta relates to a particular composition that comprises proteins having an isoelectric point in an acidic region and whose viscosity increases with temperature reduction; and Heath relates to a water-miscible gum composition comprising fine particles of gum coated with a layer of substance having a greater tendency to absorb water than the gum, such as starch and/or protein. As explained above, none of these references discloses or suggests the claimed composition, in which one or more viscosity-lowering protein is moderately hydrolyzed and is present in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature. Thus, the claims are not obvious over any of these references.

Claims 22, 26-28, 30, and 35-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,210,686 to Bell et al. ("Bell"). Applicant respectfully disagrees.

Bell relates to dictary supplements comprising yeast-derived fiber such as glucan and glucomannan, which are used for lowering the risks of heart diseases and for improving cardiovascular health in humans. Bell discloses that the dictary supplements can further

comprise various other ingredients, such as carbohydrate, protein, vitamins, minerals, antioxidants, fiber and other dietary supplements. While Bell discloses using protein and other fiber as possible additional ingredients in its yeast-derived fiber supplements, there is no disclosure or suggestion of using proteins as recited in the claims, e.g., using moderately hydrolyzed protein selected from a particular group wherein the protein is present in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature such that the composition is less viscous than the same composition in which the viscosity-lowering protein is absent.

Thus, the general mention of fibers and proteins in Bell does not render obvious the present composition of specific fibers and proteins, such that the claims are not obvious over Bell. Accordingly, the rejection over Bell should be withdrawn. Claim 30 and its dependent claims are further distinguished from Bell as reciting a composition that consists essentially of particular fibers and proteins, such that these claims are further non-obvious over Bell.

Claims 22, 24-28, 30 32, 33, 35, and 36 are rejected under 35 U.S.C § 103(a) as being unpatentable over U.S. Patent No. 3,889,007 to Gunter et al. ("Gunter") or U.S. Patent No. 4,478,658 to Wittwer").

Gunter relates to a food composition for aquatic organisms comprising fish meal and fish extracts. The composition may include a binder, such as gelatin, guar gum, agar agar, CMC, alginate ester, collagen, and pregelatinized potato starch. The Examiner states that one would have been motivated to combine guar gum and collagen because Gunter teaches that the components are useful for the same purpose. (Office Action at 15.) However, even if these components were combined, there is no disclosure or suggestion in Gunter of providing these materials in a composition in the recited manner, with the protein moderately hydrolyzed and in an amount to lower the viscosity of the fiber to less than about 500 mPas at room temperature such that the composition is less viscous than the same composition in which the protein is absent. Moreover, these materials, as binders, are used to enable the feed product to withstand disintegration or leaching from the sea water. Thus, Applicant submits that the disclosure in Gunter of guar gum and collagen as potential binders in an aquatic feed product would not suggest to or motivate a person of ordinary skill in the art to combine these materials in the recited manner to achieve the claimed composition.

Wittwer also is deficient. Wittwer relates to a method for sealing edible capsules comprising telescopically engaged tubular capsule halves that define a junction seam between them, with a frangible edible label covering the seam. The label may be prepared from a variety of film forming materials that are pharmaceutically acceptable, including natural proteins, cellulose and its derivatives, carbohydrates, vinyl polymers, acrylic polymers, natural gums, and mixtures thereof. However, such listing of certain proteins and fibers does not disclose or suggest providing a composition of particular proteins and fibers as recited in the claims.

Therefore, the claims are not obvious over Gunter or Wittwer. Also, for the reasons explained above. Applicant disagrees with the Examiner's statement that the prior art discloses "the structurally identical composition of guar gum and collagen." (Office Action at 17.) Because Gunter and Wittwer only mention using fiber and protein materials for binding and labeling purposes, and do not disclose or suggest providing a composition of particular fibers and proteins as recited in the claims, a person of ordinary skill in the art would understand that the proteins and fibers in Gunter and Wittwer, even if combined, would not be structurally identical to the claimed composition. Further, as is evident in the previous analysis of the numerous references cited by the Examiner, none of these references recognizes the advantages that are achievable in the recited use of a low viscosity composition for oral or enteral administration so that those references do not teach or suggest the features of the present invention. These references show that the state of the art is such that, in the absence of the teachings from the present invention, one of ordinary skill in the art would not know how to make a composition as recited in the present claims comprising, or consisting essentially of, one or more viscous soluble fiber(s) and one or more viscosity-lowering protein(s), wherein said one or more viscositylowering protein(s) has the ability to lower the viscosity of viscous soluble fibers in the composition such that the composition is less viscous than the same composition in which the viscosity-lowering protein is absent.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection over Gunter or Wittwer. Claim 30 and its dependent claims are further distinguished from these references as reciting a composition consisting essentially of particular viscous soluble fiber(s) and viscosity-lowering protein(s), such that these claims are further non-obvious over Gunter and Wittwer.

Application No.: 10/516,600

Claims 22, 24-28, 30, 32, 33, and 35-37 are rejected under 35 U.S.C § 103(a) as being unpatentable over U.S. Patent No. 6.287.623 to Nakayama et al. ("Nakayama").

Nakayama relates to a method for producing a protein-containing acid food and drink that includes a protein emulsion having a pH value that is higher than the isoelectric point of the protein in the emulsion at high temperature to make the emulsion having a pH value that is lower than the isoelectric point of the protein. The protein-containing acid food and drink contains protein, fat and oil, and water-soluble polysaccharide. Thus, Nakayama relates to a completely different product from the claimed composition. While Nakayama mentions including soybean fiber as an additional ingredient, this does not disclose or suggest the composition as recited in the claims, which comprises or consists essentially of particular fibers and proteins to provide particular viscosity characteristics. As explained above with respect to the other cited references, the mere disclosure of proteins and fibers as possible ingredients in these references—none of which discloses or suggests using particular proteins and fibers such as to lower the viscosity of the fibers to a certain level—does not disclose, suggest or motivate the present composition or its viscosity characteristics.

Thus, the rejection over Nakayama also should be withdrawn. Additionally, claim 30 and its dependent claims are further distinguished from Nakayama as reciting a composition consisting essentially of particular viscous soluble fiber(s) and viscosity-lowering protein(s), such that these claims are further non-obvious over this reference.

Accordingly, all rejections under §§ 102 and 103 should be withdrawn.

In view of the above, the entire application is believed to be in condition for allowance, early notification of such would be appreciated.

Respectfully submitted,

Nestle Nutrition 12 Vreeland Road, 2nd Floor Florham Park, NJ 07932 (973) 593-7553

Dated: February 2, 2010

BY /gml/
Gary M. Lobel
Attorney for Applicant
Reg. No. 51,155